CLAIMS

1. Use of solid lipidic nanoparticles (SLNs) for the preparation of pharmaceutical compositions suitable for the treatment of ophthalmic diseases by intravenous or topical ocular administration, wherein in said SLNs is incorporated a pharmacologically active substance for the treatment of said diseases.

2. The use according to claim 1, characterised in that said SLNs have a mean diameter comprised between 50 and 400 nm, and a polydispersion comprised of between 0.06 and 0.30.

3. The use according to claim 1, characterised in that said SLNs have an average diameter comprised between 100 and 200 nm and a polydispersion comprised of between 0.10 and 0.20.

4. The use according to claim 1, characterised in that said SLNs have a pharmacologically active substance content comprised of between 0.1 and 7.0%.

5. The use according to claim 1, characterised in that said pharmaceutical compositions suitable for the treatment of ophthalmic diseases by intravenous administration consist essentially of dispersions of said SLNs in isotonic aqueous solutions having a concentration of SLNs comprised between 10 and 250 mg/ml.

6. The use according to claim 1, characterised in that said pharmaceutical compositions suitable for the treatment of ophthalmic diseases by topical ocular administration consist essentially of dispersions of said SLNs in isotonic aqueous solution having a concentration of SLNs comprised between 1.0 and 25% w/v and further containing from 0.1 to 0.4 % of a viscosizing substance.

7. The use according to claim 1, characterised in that said pharmacologically active substance is selected from the group comprising: amphotericin, miconazole, ganciclovir, saquinavir, acyclovir, famciclovir, vidarabine, idoxuridine, β-interferon, paclitaxel, methotrexate, doxorubicin, angiopoietin 1, diclophenac, indomethacin, ketorolac, piroxicam, flurbiprofen, dexamethasone, triamcinolone, hydrocortisone, fluorometholone, rimexolone, timolol, betaxolol and acetazolamide.

8. The use according to claim 1, characterised in that said SLNs are prepared by a process wherein:

a) a molten lipid substance containing a drug or its complex is mixed with a mixture comprising water, a surfactant, a cosurfactant and optionally a counterion

of the drug, pre-warmed to a temperature at least equal to the melting temperature of said lipid substance, thus obtaining a microemulsion having a temperature at least equal to the melting temperature of said lipid substance;

b) the microemulsion obtained in step a) is dispersed in water or in an aqueous medium cooled to a temperature comprised between 2 and 5 °C, thus obtaining a dispersion of solid lipidic nanoparticles incorporating the drug;

c) the dispersion obtained in step b) is washed with water or with an aqueous medium by diafiltration with the practically total elimination of the surfactant and the cosurfactant;

d) the dispersion obtained in step c) is dried by lyophilisation or by spray drying or by evaporation, thus obtaining the solid lipid nanoparticles (SLNs) with the drug incorporated.

9. The use according to claim 8, characterised in that the microemulsion obtained in step a) is added to a mixture comprising water, a surfactant, a cosurfactant and a lipid warmed to a temperature at least equal to the melting temperature of the lipid and the mixture thus obtained is dispersed in water or in an aqueous medium cooled to a temperature comprised of between 2 and 5°C.

10. The use according to claim 8, characterised in that at the end of step a) a substance suitable for stabilising the SLNs is added selected from the group comprising dipalmitoyl phosphatidyl ethanolamine-PEG, diacyl phosphatidyl ethanolamine-PEG (PEG M. W. 750-2000) and fatty acids pegylated with PEG-methylethers (PEG M. W. 750-2000).

11. A therapeutic method for the treatment of ophthalmic diseases comprising the intravenous or topical ocular administration of a therapeutically effective amount of a pharmaceutical composition comprising solid lipidic nanoparticles containing a pharmacologically active substance for the treatment of said ophthalmic diseases.

12. The therapeutic method according to claim 11, characterised in that the dosage for intravenous administration is an amount of said composition containing to 0.01-5.0 milligrams of active substance per kilogram of body weight.

13. The therapeutic method according to claim 11, characterised in that the dosage for topical ocular administration is an amount of said composition containing to 0.01-5.0 milligrams of active substance for each eye.

14. A pharmaceutical composition suitable for the treatment of ophthalmic diseases by intravenous or topical ocular administration, consisting essentially of an isotonic aqueous dispersion of solid lipid nanoparticles (SLNs) having a mean diameter comprised between 50 and 400 nm and polydispersion comprised between 0.06 and 0.30, a pharmacologically active substance for the treatment of said diseases being incorporated within said SLNs.

15. The pharmaceutical composition according to claim 14, characterised in that said aqueous dispersion contains a viscosizing substance.

16. The composition according to claim 14, characterised in that said SLNs have a mean diameter comprised between 100 and 200 nm and polydispersion comprised between 0.10 and 0.20.

17. The composition according to claim 14, characterised in that for the intravenous administration, said isotonic aqueous dispersion has a concentration of SLNs comprised of between 10 and 250 mg/ml.

18. The composition according to claim 14, characterised in that for the topical ocular administration, said isotonic aqueous dispersion has a concentration of SLNs comprised between 1 and 25% w/v and contains from 0.1 to 0.4% of a viscosizing substance.

19. The composition according to claim 14, characterised in that said SLNs have a pharmacologically active substance content comprised between 0.1 and 7.0%:

20. The composition according to claim 14, characterised in that said pharmacologically active substance is selected from the group comprising: amphotericin, miconazole, ganciclovir, saquinavir, acyclovir, famciclovir, vidarabine, idoxuridine, ß-interferon, paclitaxel, methotrexate, doxorubicin, angiopoietin 1, diclophenac, indomethacin, ketorolac, piroxicam, flurbiprofen, dexamethasone, triamcinolone, hydrocortisone, fluorometholone, rimexolone, timolol, betaxolol e acetazolamide.

21.Compositions according to claim 14, characterised in that the lipid of said SLNs is selected from the group comprising trilaurine, tricapriloin, tristearine, tripalmitine, capric/caprylic triglycerides, dipalmitine, distearine, glyceryl monostearate, glyceryl palmitostearate, cetylic alcohol, stearylic alcohol, fatty acids having C10-C22 chains, cholesteryl hemisuccinate, cholesteryl butyrate and cholesteryl palmitate.